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M E M O R A N D U M

DATE: December 17, 2009

TO: Maine Board of Environmental Protection

FROM: Maine DHHS, Maine CDC

RE: Joint Rulemaking (DHHS & DEP) for Lab Certification Rules

Proposed Rule Amendments to the Maine *Comprehensive And Limited Environmental Laboratory Certification Rules, 10-144 CMR 263*

22 M.R.S.A. § 567 authorizes both DHHS and DEP to establish rules that govern the lab certification process in Maine. The following summary explains the proposed changes from DHHS, Maine CDC's Lab Certification Officer Matthew Sica.

INTRODUCTION:

The Maine Environmental Laboratory Certification Program ("MELCP") was established to help ensure that laboratories are submitting reliable and consistent data to Maine's various environmental programs. The program offers certification designed to accommodate the needs of the Departments' programs that includes testing required by the Safe Drinking Water Act, Lead Poisoning Control Act, Clean Water Act, the Resource Conservation and Recovery Act, and the Maine Leaking Underground Storage Tanks [LUST] Program.

Why are rule changes being proposed?

The MELCP is considering rule amendments to assure a high standard for the quality of data produced by laboratories engaged in environmental testing and to further clarify the intent of the current ***Maine Comprehensive And Limited Environmental Laboratory Certification Rules, 10-144 CMR 263***. Adoption of these rule amendments will ensure that Maine rules for laboratory certification are consistent with those of other states. A consistent approach to regulation of laboratories allows meaningful exchange of laboratory information between states, as well as in reporting to federal agencies. A rule consistent with national standards also allows laboratories certified by multiple states to more easily interpret the regulation and achieve compliance.

Both agencies are hoping to reopen the comment period to include rule amendments added after the public hearing on October 1, 2009.

What are the major changes proposed for Comprehensive And Limited Environmental Laboratory Certification Rules, 10-144 CMR 263?

The major changes proposed within these lab certification rules include the following:

- (1) **Updated and Increased Definitions.** The proposed amendments incorporate more definitions to ensure consistency in the use of terminology. Other terminology has been updated to reflect current usage within the environmental testing industry. For example, the term "performance evaluation" is obsolete and has been replaced by the term "proficiency testing";
- (2) **Incorporation of Current Policies and National Standards.** The proposed amendments define a consistent set of rules for the administration of the environmental laboratory review process. This update is intended to assist regulated parties to achieve compliance by incorporating several existing industry standards, along with current MELCP rules and policies. The rules also incorporate detail from existing guidance documents, which include the following:
 - Incorporation of Quality System elements, the 2003 National Environmental Laboratory Accreditation Conference NELAC standard and the International Organization for Standardization / International Electrotechnical Commission, ISO/IEC 17025:1999;
 - Allowance for performance-based methods and method flexibility, where applicable by program; and
 - Updated use of new methods.
- (3) **Proficiency Testing Requirements.** With these proposed changes, DHHS also amended the proficiency testing requirements for laboratories and proficiency test providers. Laboratories will be required to perform one proficiency test per year instead of the current rule's requirement for two tests. The NELAC Institute's (TNI) PT Board reviewed statistical data, which showed only a small increase of laboratory effectiveness, if two PTs per year occurred, compared to one PT per year. This study analyzed the pass/fail data for PT sample data sets for laboratories performing two PT samples per year and other laboratories performing one PT sample per year. This change would realize a cost savings to the laboratories, without detriment to quality;
- (4) **On-site Inspections.** DHHS proposes to amend the manner in which on-site inspections are conducted. Currently, a laboratory located in Maine could receive NELAC accreditation from another state and be exempted from the biennial onsite inspection of the MELCP. This practice limited the effectiveness of the MELCP on regulating these particular laboratories, whereas this change would require laboratories located in Maine to be inspected by the MELCP. If adopted, this change would require the MELCP to perform out-of-state laboratory inspections when the resident state's inspections are performed at a frequency of greater than two years. The MELCP would perform inspections for all of its programs, including the MEDRO/GRO program for the DEP Leaking Underground Storage Tanks [LUST] Program. Current rule does not require inspections for this program;

- (5) **Re-organization of the existing rules.** With this proposed rule change, DHHS amended the organization of the rules themselves, in order to reflect the general sequence of the certification process, which promotes clarity and helps achieve compliance; and
- (6) **Expansion to include RCRA.** DHHS and DEP propose to expand scope of the certification program to include RCRA methods. This proposed change would give added confidence to MEDEP programs which require the use of solid and hazardous waste data. This addition occurred after the public hearing, after public comments were received from both DEP and DHHS.